

United States Department of Agriculture July 9, 2001

## CENTER FOR VETERINARY BIOLOGICS NOTICE 01-06

Marketing and Regulatory Programs

Subject: Issuance of Revised *RelPot* Software and Supplemental Assay Method

Animal and Plant Health Inspection Service

To: Biologics Licensees, Permittees, and Applicants

Veterinary Services Management Team Directors, Center for Veterinary Biologics

Veterinary Services

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Federal Relay Service (Voice/TTY/ASCII/ Spanish) (800) 877-8339 The purpose of this notice is to inform interested parties that the Center for Veterinary Biologics (CVB) is issuing a revised version of the U. S. Department of Agriculture Veterinary Biologics Program's Relative Potency Calculation Software (*RelPot*) that is used in calculation of *in vitro* relative potency antigen quantitation assays and is updating the corresponding Supplemental Assay Method (SAM) to reflect the software revision. The effective date of version 3.1 of *RelPot* is July 9, 2001.

Version 3.1 of *RelPot*, like the previous versions, operates on an IBM or IBM compatible computer under DOS or Windows 3.1/95/98/Millennium Edition operating system. It is not compatible with Windows NT or Windows 2000. No change, other than to correct a mathematical error in the calculation method, has occurred in version 3.1, rather several user enhancements have been added and other programming errors corrected.

MVSAM0318.02. Supplemental Assay Method for Evaluation by the Relative Potency Method of *In Vitro* Enzyme Immunoassays Used in Testing of Veterinary Vaccines. This document supersedes the March 19, 1998, version. Appendix A has been updated to reflect different computer media available for distribution and the mathematical calculation of the relative potency for positive slope assays has been corrected. Previously, the relative potency value method listed for positive slope assays was the inverse of the correct calculation method.

Previous users who had received version 3.0 of the *RelPot* software from the CVB have received a mail notice of the new version and have been provided a method to receive the revision. Other interested parties who wish to receive the revised version, but have not received notification, should complete Appendix A of SAM 318 and mail that form to the CVB.

This SAM is also available as an Adobe Acrobat pdf file on the world wide web (WWW) at <a href="http://www.aphis.usda.go/vs/cvb/lab.">http://www.aphis.usda.go/vs/cvb/lab.</a>

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For those firms and interested parties with E-mail addresses and WWW access to the SAMs, this notification has been sent via electronic mail. If you would prefer to receive information from the Center for Veterinary Biologics via electronic mail, please send your E-mail address to cvb@aphis.usda.gov.

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